ADVISORY COUNCIL FOR THE ELIMINATION OF TUBERCULOSIS (ACET)
Centers for Disease Control and Prevention (CDC)
Atlanta, Georgia

February 4 & 5, 2003

Minutes of the Meeting

The Centers for Disease Control and Prevention (CDC) convened a meeting of the Advisory Council for the Elimination of Tuberculosis (ACET) February 4-5, 2003 at Corporate Square in Atlanta, Georgia. Those present were:

ACET Members/Liaisons	Meeting Participants	Meeting Participants, cont.
Charles Nolan, Chair	Rachael Albalak	
Stephanie Bailey	Greg Andrews	Lilia Manangan
Eric C. Blank	Jose Becerra	Suzanne Marks
Henry M. Blumberg	Gabrielle Benson	Scott McCoy
Joanne Carter	Amy Bloom	Stuart McMullen
Fran Du Melle	Diane Bennett	Scott McNabb
Wafaa M. El-Sadr	Betty Boulder	Laurie Mignone
Anne Fanning	Ken Castro	Marisa Moore
Masae L. Kawamura	Amy Copetto	Mary Naughton
James Mcauley	Viva Combs	Tom Navin
Gene Migliaccio	Dave Crowder	Norman Neiol
Carol J. Pozsik	Nick DeLuca	Lisa Nelson
Randall Reves	Teresa Durden	Rick O'Brien
Sarah Royce	Thena Durham	Kate O'Toole
Rachel L. Stricof	Reginald Edwards	Walter Page
Charles Edward Wallace	Edward Ellis	Adelisa Panlilio
Evon Johns	Sue Etkind	Paul Poppe
Sheryl Mason	Angela Fazah	Cathy Rawls
Warren W. Hewitt, Jr.	David Fleming	Maria Rios
Sheldon Morris	Alstead Forbes	Brandaly Rodriguez
Gary A. Roselle	Paulette Ford-Knights	Lisa Rosenblum
James Cheek	Maria Fraire	Dan Ruggiero
Lee Reichman	Judy Gibson	Joe Scavotto
Diana Schneider	Paul Halverson	Sarah Schmit
	Michael Hatcher	Eva Seiler
	Andy Heetdarks	Robin Shrestha-Kawahara
	Gina Hill	Don Sinisi
	Michael Iademarco	Sarah Sitarek
	Kashef Ijaz	Ligail Starks
	Harold Jaffe	Zach Taylor
	John Jereb	Rita Varza
	Yvette Johns	Andy Vernon
	Kristin Jones	Elsa Villarino
	Heather Joseph	Geoffrey Wallace
	Steve Kammerer	Stephanie Henry Wallace
	Dolly Katz	Wanda Walton
	Ram Koppaka	Kevin Winthrop
	Mark Lobato	Ronald O. Valdiserri

Opening Session: Welcome and Introductions

Chairman Charles Nolan called the meeting to order on February 4, 2003 at 8:34 AM. Members, liaisons, and guests were welcomed and asked to introduce themselves. There were new members present at the meeting. Dr. Ken Castro advised the group that there would be a Brown Bag Seminar on The California TB Outbreak Response Plan during lunch. Dr. Harold Jaffe expressed thanks on behalf of the council for Dr. Charles Nolan's hard work and dedication as the Chairman of the Advisory Committee on TB Elimination. He has served since June of 1998 and the group thanked him for doing such a good job. Dr. Masae Kawamura will be assuming the role of Chair.

Dr. Harold Jaffe
Update on the National Center For HIV, STD, and TB Prevention (NCHSTP)

Dr. Harold Jaffe gave an update on major personnel changes and other activities at NCHSTP, indicating that Dr Julie Gerberding now has a new management team in place in the Office of Director (OD) at CDC. The team is comprised of the following members:

- Dr. David W. Fleming has been named the Deputy Director for Public Health Science.
- Dr. Edward Thompson has been named the Deputy Director for Public Health Services.
- William H. Gimson has been named the Chief Operating Officer.
- Kathy Cahill has been named the Senior Advisor for Strategy and Innovation.
- Verla S. Neslund has been named the Acting Chief of Staff.
- Recruitment has been underway for quite a while to recruit a Director for Division of HIV/AIDS Prevention: Intervention Research and Support. The finalists have been interviewed and an offer will be made soon.

On January 24, 2003 the CDC staff, including Dr. Ken Castro, briefed the staff of the House Energy and Commerce Committee on CDC's global AIDS, TB, and Malaria activities. On January 21, 2003 the CDC was visited by the Science and Technology Committee of The British House of Lords. They came to CDC to be briefed on a variety of Infectious Disease issues, including the CDC's Domestic and Global TB Prevention Control and Research Activities. The TB briefing was a good opportunity to describe how surveillance, program support, training, and research can work synergistically in TB control. A Congressional staff briefing was requested by Representative Sherrod Brown for February 14, 2003 focusing on global TB. Representative Brown has successfully proposed legislative action to have the U.S. engaged in the global fight against TB.

Regarding the budget and legislative issues, the federal government is continuing to operate under a continuing resolution. The latest runs through February 7, 2003, which permits CDC to operate under the same general provisions, or level of funding, as in 2002. The Senate Appropriations Subcommittee on Labor Health and Human Services Education recommended on

January 23, 2003 a total budget for CDC's HIV, STD, and TB prevention effort of $1.168 billion dollars. This is $3 million above the 2002 level, which was above the administration request.

The bill would provide for an increase of $5 million for global AIDS, 3 million for STD's, and a $5 million dollar increase for Tuberculosis in 2003 if the budget is passed.

The Senate's recommendation to increase TB funding is directed to implement the Institute of Medicine (IOM) recommendations, to encourage CDC to partner with private foundations on research, and to work with Immigration and Naturalization Service (INS) to develop novel TB screening strategies. The President's budget for FY2004 was delivered to Congress. The TB request was $131 million dollars which is $1.3 million less than the 2003 request. It does not take into account any increases that may occur in the 2003 budget. The global fund to fight AIDS, TB, and Malaria was announced in Geneva during their second round of grants worth $866 million, over 23 years, for programs in 60 countries.

In addition, the Secretary of Health and Human Services Tommy Thompson, was elected as chair of the board of the Global Fund. On January 30, 2003 Senator Richard Durbin introduced the Global Coordination of HIV/AIDS Response Act. This bill would authorize a total of $3.35 billion, of which $2.1 billion in the 2004 budget would go towards the global fund. The general accounting office is beginning a review of CDC science committees. The entrance conference was held on January 29, 2003. Three objectives were stated in the review:

- Determine the role of science advisory committees in the development of national policies and regulations, and how they vary in size, scope, authority, and issues;
- Determine what policies or procedures to use to ensure scientifically sound, independent, and balanced advice; and
- Decide what improvements in policies or procedures could better support these goals across the agency.

Dr. Ron Valdiserri
ACET Membership Update

Dr. Ron Valdiserri provided an update on new committee membership and recognized those members who would not be returning. For the following, this was the last meeting of attendance:

- Dr. Stephanie Bailey
- Dr. Charles Wallace
- Dr. Charlie Nolan
- Dr. David Cohn (not in attendance)
- Mrs. Vinnie Gee (not in attendance)
- Mrs. Christinia Larkin (not in attendance)
- Dr. Michael Richardson (not in attendance)
- Dr. Larry Sanders (not in attendance)

The following members have been re-appointed or are new members:

- Dr. Masae Kawamura, Director, TB Control Section, San Francisco Department of Public Health, reappointed as the Chair
- Dr. Wafaa El-Sadr, Director, Division of Infectious Diseases, Harlem Hospital Center, New York, New York
- Dr. Jeff Douglas, Infectious Disease Consultant, Kingsport, Tennessee
- Dr. Michael Fleenor, Health Officer for Operations, Jefferson County Department of Health in Birmingham, Alabama.
- Mrs. Theresa Ann Garret, R.N., M.S., Director/TB Control Officer, Bureau of Communicable Disease Control, Salt Lake City, Utah
- Dr. David Gonzalez, Associate Professor, Department of General Internal Medicine, University of New Mexico School of Medicine, Albuquerque, New Mexico
- Harriet Gray Highsmith, Nurse Consultant, Office of Emergency Preparedness and Response, State Department of Health and Mental Hygiene
- Sarah Loaiza, Managing Partner, Latino Healthcare, South Pasadena, California
- Eileen C. Napolitano, Deputy Director, New Jersey Medical School National TB Center, University of Medicine and Dentistry of New Jersey, Newark, New Jersey
- Dr. Stephen Mark Puentes, Assistant Director, TB Control Program, Los Angeles County Public Health Program, Los Angeles, California

Dr. Ken Castro
DTBE Directors Report

Dr. Ken Castro referred to the goals that have been outlined in the CDC response in the Institute of Medicine Report (IOM) entitled *Ending Neglect.* The Institute of Medicine gave five recommendations including maintaining control, accelerating the rate of decline, developing new tools, increasing global involvement, and mobilization. In addition, he reviewed the program/ infrastructure support for the year 2002. This included Epi-Aids outbreaks, TB in low incidence, and the program evaluation (NTCA 2002 workshop). In terms of policies, training, and education, the three model centers are continuing to be supported. The program managers training took place in October of 2002, and web-based publications continue to grow and can be downloaded from the web site.

The *ATS/CDC/IDSA TB Treatment Guidelines* are scheduled for publication in the *American Journal of Respiratory and Critical Care Medicine,* and will be subsequently published in the *MMWR*. The January 2003 *QFN Guidelines* were distributed to the group in the *MMWR*. The *Infection Control Guidelines* are in clearance, and they include ACET suggestions to use one or other PPD products consistently. Changes may lead to difficulties interpreting differences in reaction sizes and avoids FDA concern.

There are several new projects to accelerate the rate of TB decline. They include addressing low incidence areas, Southeastern and U.S. born African Americans, INS detainees, improved electronic monitoring of class B1 immigrants and refugees, aggregate monitoring (ARPEs), and

the solicitation 2003-N-00706 announcing CDC funds to provide genotyping of *M. tuberculosis* isolates. In the area of development of new tools, Dr. Castro referred to the article in the *EID* special issue: vol. 8, No. 11 November 2002 entitled *Genotyping Surveillance Network Reports.* Latent tuberculosis infection tests continue to be evaluated, in particular the second generation of QFN-2® and ELISPOT. The TBESC has been very busy planning the ideal way to obtain optimal collaborative structure like has been obtained in the TB Clinical Trials Consortium.

In reference to increasing global involvement, technical support has been given to 16 countries. The focus has been on the countries that have had the majority of reported foreign-born cases individuals in the U.S. originate from. Those countries are Mexico, Vietnam, and the Philippines. Other countries included in the global involvement are India, Brazil, and Russia (expand DOTS access), Baltics, Russia, and Peru (MDR-TB), and the area of TB/HIV Botswana, as well as the GAP missions. In terms of mobilizing support, the continuance of working with external partners is important in TB elimination. Some other key areas are the Congressional briefings, World TB Day 2003 plans, media communications related to guidelines, scientific publications, and the development of media guidelines for outbreaks. In reference to the goal of tracking progress in TB elimination, the annual morbidity/mortality data is relied heavily upon. The other area of focus is the completion of therapy, and seeking consistency with HP 2010.

Discussion Points:

It was noted as a matter of opinion that the tuberculosis skin test does very poorly in a low incidence setting. A comment was made to target high-risk populations rather than low risk. The only exception in is health care workers. Ideally, the risk assessment should be relied upon before deciding to test everyone consistently. It was noted that the products are tested by the FDA and in order to change the label, there must be definitive data. There have been a lot of reports in journals that in certain situations, there is differential reactivity. However, there has not been enough definitive data at the FDA to change the labels.

Ms. Rachel Stricof noted that it is difficult to obtain data without access to the technology to evaluate the product. She suggested that the FDA assist state and local health departments by evaluating specific tuberculin vials associated with false positive results. It was also noted that the CDC's study demonstrating no difference among the products only involved 1500 people. They may not have had the power to detect a difference, especially when compared to the amount of testing going on in hospitals across the nation.

Dr. Charles Nolan addressed issues about the funding gap. Dr. Castro stated that within each goal set forth, many objectives will be accomplished. However, every objective listed may not be reached. Mobilizing support will be crucial, and priorities will be constantly assessed.

Dr. Charles Wallace requested information on the federal partners involved in moving this agenda toward completion and fulfillment. Dr. Castro stated the importance of orchestrating activities to avoid duplication of efforts, as well as to achieve the synergies that are achievable by mixing resources toward a common goal.

Ms. Fran DuMelle
Report on Current Domestic TB Legislation

Ms. DuMelle gave an update on legislative action in the 108th Congress. Legislation that will likely be reintroduced from the 107th congress (TB Elimination Act) is based on the IOM report. A group was convened from the National Coalition for the Elimination of Tuberculosis (NCET) to determine the opportunities for inserting IOM recommendations into authorizing language. The major areas that the IOM addressed were the adequate funding needs. It was decided to retain categorical federal funding. Resources for research is another critical point that IOM targeted for new diagnostic tools, treatment for latent infection, and development of a vaccine. Previous authorizing language refers to the national program as Preventative Services for Tuberculosis Control Projects, while the current proposed authorizing language refers to the national program as the National Program for Tuberculosis Elimination.
There were several items that needed to be added to the authorization bill as the IOM report was reviewed. The first of these were to:

- Provide the Secretary with advice and council in terms of making progress in the goals of elimination;
- Look at a national plan to update and refocus all areas pertaining to the elimination of TB, and to make this an ACET responsibility; and
- Address the application of new technologies and review progress toward elimination.

It was felt that international TB control efforts could be maximized if they were generated from a central location and included ACET recommendations. The focus of international TB control efforts would be primarily in countries of high incidence that directly affect the U.S. The research and demonstration section of the authorizing language was expanded to delineate more of the activities carried out by CDC. Priority will be given to research conducted through the TB Epidemiologic Studies Consortium (TBESC) and the TB Consortium (TBTC) at CDC. This was to gain recognition for the in-house research capacity at CDC, and to gain some recognition for the ongoing activities at CDC. Also addressed were public education programs, support of model centers, and collaboration with international organizations in coordination with USAID. In reference to reports, the Secretary, acting through CDC and in consultation with ACET, shall report on a biennial basis activities carried out under this section.

With regard to the National Institutes of Health (NIH), there are 3 areas of focus. The National Heart, Lung and Blood Institute is to bring back the tuberculosis academic awards and to create a new award entitled *Tuberculosis/Pulmonary Infection Awards*. This is to refocus the research activities. The National Institute of Allergy and Infectious Diseases (NIAID) recognizes the recommendations from the blueprint for TB vaccine development. Fogarty International Center is also a strong partner in the global initiative.

Discussion Points:

In response to an inquiry regarding program leadership, Ms. DuMelle stated that the program was under the leadership of ALA and ATS with NCET doing the grassroots activities. The sponsors have been lined up, but she was not prepared to name them at this time. The people who are primarily targeted are still in the high incidence TB areas, and CDC has complete authority for Global Initiatives and to recognize CDC activities.

Charles Wallace requested that Ms. DuMelle comment on the bills and how far they are than they were during the last update. Ms. DuMelle responded that they are caught up in issues beyond their control because of all the effort being spent on bioterrorism. There is a concerted effort underway to make TB control and TB elimination legislation understood by the members of Congress. They are in the final stages of developing a protocol for Congressional visits to their back home territories.

Dr. Wallace expressed concern with the fact that Members of Congress are rarely available to hear issues of TB elimination. Ms. DuMelle responded to this concern by expressing the importance of having partners to help form coalitions. It is important to bridge and build linkages with existing partners as well as develop new coalitions, especially in high-risk areas.

Dr. Warren Hewitt noted the importance of developing a strategy at federal and local levels to garner more funding for tuberculosis. A concern was raised about the situation in Texas regarding the freezing of local and federal dollars in certain areas. It was noted that as state dollars are realigned, they may be replaced with federal dollars.

Dr. Michael Iademarco
Update on Infection Control Guidelines

Dr. Iademarco delivered an update on the revision of the TB Infection Control Guidelines. The document has been aligned for consistency and format and has recently entered clearance. The previous guidelines have been developed in light of the decreased TB case rate, decreased MDR, fewer patients requiring hospitalization, increased care in outpatient treatment settings, and less nosocomial transmission being reported. In addition, there has been new research on various infection control strategies and the revision was initially recommended by ACET. The revision process required the need for consensus. This has been a 2 ½ year process, which has included multiple CDC meetings, 2 public meetings with invited experts, presentations at several professional meetings, and now has entered the initial phase of CDC clearance.

Obtaining cross-clearance among the different CIOs at CDC will take time. Dr Iademarco briefly reviewed the different CIOs. Following CDC clearance the draft will be distributed to ACET and HICPAC for review and comment. After considering ACET's and HICPAC's comments, a draft will be published in the Federal Register for public comments. This will be carried out under the leadership of Wanda Walton in the Communication and Education Branch. Depending on the nature of the changes resulting from public comment and how significant they are, there may be a need to resubmit through CDC clearance. The final document will be

published in the *MMWR Reports and Recommendations.* The need will then be to proceed with developing supplemental education materials. The timeframe is estimated to be as follows:

- ⊄ Present to April 2003: CDC Clearance
- ⊄ May 1, 2003: Distribution to ACET and HICPAC
- ⊄ June 1, 2003: Federal Register
- ⊄ November 1, 2003: Revisions Made
- ⊄ December 1, 2003: Formative Evaluation
- ⊄ January 15, 2003: CDC Re-clearance
- ⊄ February 2004: Publication

The potential challenges to the consensus at this point are issues of fit testing, periodic fit testing, overlap with many other DTBE guidelines, the need for consistency with the evolving national bioterrorism guidelines, and the challenge of the length of time needed for the entire process from the beginning. Another challenge is the size of the document. The current draft is147 double spaced pages with 13 sections; 8 supplements; 57,000 words; and 350 references.

New guidelines have incorporated changes in laboratory techniques; delivery of services in outpatient non-facility-based settings; QTF testing; recommendations for moving into and out of isolation; voluntary use of respirators by visitors; and frequently asked questions and glossary sections.

Discussion Points:

It was noted that HICPAC requested a copy of the guidelines simultaneously with ACET prior to their publication in the Federal Register. There are two federal advisory committees at CDC who have requested the opportunity not only to see, but also to give input prior to publication in the Federal Register.

A question was raised about the resolution process when two or more cross clearance entities have contrasting views or recommendations. Dr. Iademarco stated that in the revision process, comments and suggestions could be divided into two categories. One is a required category and the other a suggested or non-required category. Depending on the intensity of the professional disagreement, there is a precedent for working those items out. Dr.Valdiserri added that the clearance chain goes upward; ultimately it will be the agency that makes the determination. The practice is to try and resolve issues at the lowest level possible.

A comment was made regarding the importance of not being lead astray by one single strong comment. If that occurs, more input will be needed to re-document and establish the balance that is necessary. Ms. Stricof expressed concern with the time delay in getting the guidelines out. Given the on-going problems with frequent, unnecessary tuberculin testing in low risk facilities and applicability for bioterrorism planning, practitioners could truly benefit from the new guidelines. She suggested using more of the HICPAC model where it is the advisory group that can intervene in developing the guidelines, and rate the various recommendations based on the literature. It becomes the expert advisory council that prepares the guidelines, which does not have as many political layers. Noted was that in the past, CDC could issue guidelines in a much

more effective and timely manner so that the guidelines could stay consistent with the science. Now it seems as though the guidelines will be out of date by the time they are released. In response Dr. Iademarco explained that these guidelines are so large and comprehensive, that this is the usual timeframe for something that is so broad in scope.

Dr. Castro pointed out that the new science is not always crystal clear, and that there is typically contention when the scientific basis is not really clear. Now there is an issue about the true efficacy of personal protective devices, and some of the new science has not been widely accepted. The document will be out for public comment, and it is highly likely that it will not require a CDC re-clearance.

Dr. Kawamua requested information about where the national bioterrorism standards are. The standards must be similar to each other. Ms. Stricof stated the TB guidelines should be used for smallpox and other organisms potentially transmitted by airborne droplet nuclei. HICPAC is looking for guidance from CDC's TB guidelines.

The comments from ACET will be evaluated before the document is being sent to the Federal Register. The ACET comments need to be back in between May and June. Dr. Nolan stated that the deadline may come prior to the next ACET meeting. Members will need to review it individually.

Paul Jensen has been assigned the job of shepherding the clearance of this document as opposed to the normal administrative system, given the complexity and size of the document. It is the hope that the personnel management with this clearance map will get the greatest efficiency out of the system. Following clearance, the final document will not come back through ACET before final publication. An informational copy will be forwarded to the members.

Dr. Ed Thompson
Welcome from Deputy Director for Public Health Services

Given that Dr. Ed Thompson was called away to an urgent meeting, his presentation was postponed.

Dr. Joanne Carter
Report on Current International TB Legislation

Dr. Carter first explained her organization and how it is involved in national and international TB advocacy. She is the legislative director of a grassroots advocacy organization called Results. It has grassroots members and volunteers in about 100 U.S. cities, and approximately 5 other countries. These cities carry out advocacy work with the Congress and local press to build support in their local communities. The mission of the organization regards issues related to hunger and poverty. The group began work on TB as an issue that disproportionately impacts poor people. TB was not getting much attention, particularly on the international side within the federal budget and the U.S. Congress.

Regarding the legislative history, Dr. Carter reviewed the process on international TB control funding. In 1997, it was about $1 million dollars for international TB funding. In 2002 it was at a level of $75 million. Between 2001 and 2002, funding jumped from $22 million to about $60 million, which is encouraging. There was legislation introduced as a companion to the domestic bill that was discussed earlier, that was introduced in the House and the Senate, the Stop TB Now Act. In an effort to address the global TB epidemic, Representatives Sherrod Brown (D-OH), Connie Morella (R-MD), and others introduced the STOP TB Act (HR 1168) in the House. Senators Daniel Inouye (D-HI), Ted Stevens (R-AK), Kay Bailey Hutchison (R-TX), Ted Kennedy (-MA) and Jon Corzine (D-NJ) introduced the Stop TB Act (S1116) in the Senate. This legislation authorized $200,000,000 for the fiscal year 2002 with the majority of funds to be used for the direct implementation of directly observed treatment short course (DOTS) tuberculosis control programs on-the-ground. Resources are to be used in developing countries having a high incidence if TB. Resources are also to be used to finance the Global TB Drug Facility created by the STOP TB Partnership and housed at the World Health Organization (WHO) that would provide critical TB drugs to poor countries that re-implementing DOTS programs.

The International Tuberculosis Control Act of 2002 (S. 2045) was then discussed. This bill introduced by Senators Barbara Boxer (D-CA) and Gordon Smith (R-OR), amends the Foreign Assistance Act of 1961 to revise requirements for assistance for health programs in developing countries. It also declares that Congress recognizes the means to control and treat the growing international problem of TB by implementing the Global Plan to Stop Tuberculosis and investing in new mechanisms like the Global Tuberculosis Drug Facility. This makes it a major objective of the foreign assistance program to control the disease. This bill authorizes $200 million for 2003 and 2004 and provides specified amounts of funds for anti-tuberculosis drugs, supplies, patient services, and training in diagnosis and care in order to increase directly observed treatment short course (DOTS) coverage, including funding for the Global Tuberculosis Drug Facility.

The United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2002 (S2525/HR 2069) was introduced by John Kerry (D-MA), Bill Frist (R-TN), Joseph Biden (D-DE), Jesse Helms (R-NC) and others. This was introduced as comprehensive AIDS legislation. The TB section of this legislation authorizes $150 million for international TB control programs in 2003 and $200 million in 2004. This bill was passed by the full Senate but did not have the chance to pass.

Dr. Carter stated that work on international TB has actually drawn money into more domestic issues. The need to expand and drive the global issues has increased the domestic issues. With the emphasis on HIV/AIDS, it is imperative to recognize the links with TB in education.

Discussion Points:

Dr. Charles Wallace asked about the possibilities of treatment for those coming from Mexico to the United States. Dr. Carter was commended by the group for her advocacy and hard work in bringing TB to the forefront in legislation. Dr. Carter stated that politics all come down to the

local level, and that educational work is crucial. The importance of cultivating and enhancing more advocates for this process was stressed.

It was noted in reference to legislation, senior staff are more crucial than most members, given that they are the ones who get the members "on board" for a particular issue. Dr. Carter was asked if there were any particular senior staff members on the Appropriations and/or the Oversight Committees to whom a better understanding of TB could be presented. Dr. Carter responded that on the House side, in terms of energy and commerce, Sherrod Brown's office would be a good place to start as they are very much focused on this effort.

Mr. Michael Qualls
Report on the TB Coalition for Technical Assistance

As part of the global effort to control Tuberculosis, 6 organizations involved in TB have formed a unique and freestanding partnership called the Tuberculosis Coalition for Technical Assistance (TBCTA). Each of the partner organizations has a TB specific agenda, expertise, and experience. Together, the TBCTA forms a formidable force that can stimulate political commitment and provide strategic direction and leadership, technical expertise, and related resources to the global effort to reduce the burden of TB. The 6 partner organizations in the coalition include: The World Health Organization (WHO); The International Union Against Tuberculosis and Lung Disease (IUATLD); The American Lung Association (ALA); The American Thoracic Society (ATS); The Centers for Disease Control and Prevention (CDC); and The Royal Netherlands Tuberculosis Association (KNCV).

The purpose of TBCTA is to: 1) Substantially improve and expand the capacity of USAID to respond to the global TB epidemic by providing state-of-the-art, context appropriate, technically sound, cost-effective consultation, and technical assistance to high incidence countries and USAID missions; 2) Complement and enlarge upon existing global TB control efforts; and 3) Reduce the global burden of TB and it's attendant mortality thus significantly improving human health, well being, and development, particularly among the poor.

The mission of the TBCTA is to enhance the political commitment and the ability of national health programs to have an impact on the global burden of TB. Along with other global TB partners, the TBCTA aims to accelerate DOTS expansion by reaching the global targets of at least 85% cure and 70% detection of infectious cases in selected countries by 2005 rather than 2015, the current target. This will be accomplished by the current 6-member coalition, and through an expansion of partnership, especially in high-burden countries and through national programs for TB control. The TBCTA is achieving this mission by providing consultation and technical assistance to USAID's field missions, global and geographic bureaus, public and private Stop TB partners and initiatives, and others to better design, implement, monitor, and evaluate TB programs and interventions. The TBCTA also assists in the identification, synthesis and dissemination of lessons learned and best practices.

TBCTA assistance has 2 major themes: 1) Provision of technical assistance; and 2) Assistance with capacity-building at the individual, organizational, institutional, and programmatic levels. In carrying out its mission, the TBCTA focuses on its value added role and upholds an

environment conducive to innovation, capacity-building, coordination and collaboration, and genuine respect for its partners, other agencies, and the communities served. The areas of expertise in activities undertaken by the TBCTA include advocacy, technical assistance, national training courses, task force training, developing training materials, regional meetings, international meetings, operations research projects, drug resistance surveys, and field Support activities.

A special unit has been formed within the TBCTA called the Task Force Training (TFT). This unit was established to support national TB programs, academic and medical institutions, strengthen human resource development in TB control, and reach and maintain the overall program. The work of the TFT forms part of the overall global plan for DOTS expansion. The TFT works to support the guidelines in generic materials that can be used or adapted in international courses and training programs supporting human resource development for national TB programs in individual countries. These strategies are being accomplished by strengthening, supplementing and expanding ongoing training activities. The TBCTA assistance plan for collaboration with USAID on TB control and regional support was awarded to KNCV on September 29, 2000. Currently, the budget ceiling for this agreement is almost $28,162,200. To date, approximately $20,883,000 has been obligated for activities in 23 different countries.

Discussion Points:

An inquiry was made regarding the primary activity that TBCTA is carrying out in the different countries. Mr. Qualls stated that it depends on the country. The TBCTA was established to support USAID. It depends on the country's mission, or the geographic or regional bureaus. One country may need capacity-building, another may need assistance with political commitment, and another may need advocacy.

A question was posed about the technical assistance that is provided after the initial assessment. An example was given of Uganda, where the mission decided that a lot of help was needed. The coalition is dependant upon the needs of the country. It has been difficult for TBCTA to go to some countries because they have been politically incorrect for the U.S. to help. However, these countries do need assistance.

A recommendation was made about the training that the TBCTA conducts, in that it is desperately needed. Helping countries develop strategic plans for human resource development is critical. This protects the health care workers as well as the individuals they treat. Many group members then raised questions pertaining to the contribution that is made to fight TB from the countries that TBCTA is assisting. Mr. Qualls stressed that the countries are not completely dependant on U.S. dollars to fight TB.

Dr. Susan Maloney
Overseas TB Screening and State-side Notification Process

The Division of Global Migration and Quarantine (DGMQ) is responsible for the regulatory authority with overseeing the quality of the TB screening assessment. They also have some regulatory authority in notifying states when immigrants and refugees will be arriving in the

United States who have suspect TB. DGMQ is focusing on maintaining TB control among foreign-born persons. The number of foreign-born cases of individuals living in the United States has grown tremendously over the last 3 decades, which is in excess of 25 million, and foreign born persons make up more than 10% of the U.S. population. More than 50% of the TB cases in the United States are among foreign born persons.

Dr. Maloney reviewed the estimated migrants entering the U.S. Over 61 million migrants cross the border into the United States annually. The majority of these are temporary visa holders (30 million), and about 30 million are visitors that are not required to have visas. Approximately 400,000 are immigrants and refugees that are entering the U.S. on visas to establish permanent residence. There are approximately 275,000 (this is a low estimate) undocumented immigrants that enter the U.S. annually, and there about 7 million living in the United States. There are also 305,000 status adjusters in the U.S. Status adjusters are people who have a visa, other than a permanent residence visa, who are applying in the U.S. to become permanent residents. Of these groups immigrants, status adjusters, and refugees are the only persons that are screened at the present time. The total number of people screened for TB before they enter the U.S. is approximately 700,000 which is about 10% of foreign born persons entering the United States annually. The following is an explanation of those holding non-immigrant temporary visas:

Visitors not requiring visas:	30,000,000
Non-immigrant visas:	30,174,627
&Temporary visitors	27,766,580
&Temporary workers/family	458,519
&Students/family	598,520
&Transit aliens	365,607
&Treaty traders/family	144,572
&Foreign government officials	126,543
&Other	714,286
&Undocumented visitors	?

AA immigrants and refugees from overseas are required to undergo a medical examination which includes screening for tuberculosis. The exam is performed by physicians who live in the countries of origin of these foreign born persons. The physicians are called “panel physicians.” One of the screening requirements is for TB. The screening is a chest x-ray followed by sputum smears if the x-ray indicates any abnormality. Following classification, the immigrants and refugees enter the U.S. and their paperwork is reviewed by either INS workers at the port of entry, or by quarantine station officers. This paperwork is then sent to the health departments for any immigrant or refugee who has been classified as having suspect TB over seas. There are different types of classification. A person can be classified as having no TB, inactive TB (class B2), or active TB by chest x-ray. Those persons classified as having active TB, must undergo 3 AFB sputum smears. If all of the smears are negative, one is classified as a noninfectious active TB case (class B1). If the smears are positive one is classified as infectious TB (class A). A class A TB person must demonstrate 3 negative smears before he/she can travel to the U.S. There is no legal requirement at this point in time for those individuals to get treatment.

Dr. Maloney discussed the identification and notification of arriving immigrants and refugees. Immigrants can enter the U.S. at any port of entry, and there are over 295 ports of entry in the U.S. Due to the lack of staffing at the ports, the DGMQ depends on the INS staff who are meeting the immigrants and reviewing their paperwork, to recognize the public health stamp. This paperwork is then mailed to the Division of Quarantine. Between 10 and 30% of this paperwork is lost before it gets to the Division of Quarantine.

Stateside Notification for Migrants with Suspect Tuberculosis:
Notification process:
- &Quarantine station to state of intended residence.
- &Follow-up forms for stateside evaluation findings (CDC 75.17)

IMP database:
- &Data for TB and refugee notification to state/local jurisdictions
  - &DS-Forms
    - &Overseas medical examination (medical conditions and classification)
    - &Arrival date, destination state (+- contact information)

Pilot electronic notification:
- &Improve notification process
  - &Prevent missed notifications
- &Evaluate efficacy of overseas screening
  - &Improve capture of stateside follow-up evaluation

In the FY 2001 there were approximately 11,000 immigrants and refugees with TB. In the FY 2002 There were approximately 8,300. There was a decrease in numbers between 2001 and 2002 but this is also a result of September 11th and a decrease in numbers of foreign persons coming into the U.S. Previous studies of these groups has shown the yield from follow-up is very high. Studies have shown between 4% and 14% of B1s have active TB within one year of arrival, and between .3% and 4% of the B2s. The Division of Global Migration and Quarantine is very committed to working with the states to improve and optimize the notification process.

Discussion Points:

A point of clarification was made that there are two B classifications, B1 and B2. B2 classification means that the individual entering has an abnormal chest x-ray but has been determined not to have active TB, which is subjectively determined by the panel physician.

Noted was that it is a great idea to identify these people and then follow-up. Yet, they can not ethically or legally refuse a permanent visa to those who have latent TB infection. A question was raised about the certification and training of the panel physicians. The panel physicians are appointed by the embassies, and they are evaluated by the Division of Quarantine staff. A problem with this is that only a certain number of sites are evaluated. The evaluation is based on the number of people coming from a particular country, and the burden of HIV/TB on that country. There are immigrants and refugees that are cleared, but the problem arises when they

develop TB on the way to the U.S. Some travel for a year or more to come to the U.S. This is a major problem. After the panel physician does the screening, the paperwork is then sent to the embassy. There is no link from the embassy to the Division of Quarantine, so those at the ports do not know when a particular person may be arriving. There does need to be a link to the embassy.

In terms of overseas screening, the tools need to be improved. The problem with the sensitivity is not with the technical expertise of the panel physicians. The notification part of the process (letting health departments know when a person with suspect TB will be arriving) can be improved. Dr. Castro acknowledged that the tools are the weak link in the chain. The results show that once a person is categorized, the agency is doing a good job of not allowing those persons in without categorization. There is, however, room for improvement. There are several items in the recommendations in the report by the IOM that have not been appropriately funded to undertake.

Dr. Castro made a recommendation to require a certification process of panel physicians and civil surgeons, to have some assurance that they are familiar with the technical requirements for evaluating individuals for the presence of TB. The Division of Quarantine has looked at two provisions that are currently in the works. One is requiring immigrants to come through the A ports that the refugees come through. The other is developing a central resource with the INS.

A question was raised about those individuals who are seeking asylum. It was stated that this group does not have to go through the screening, and a refugee never has to adjust his/her status. A lot of cases are also being seen in overseas adoption, given that foreign born children with positive TB strains are adopted to American parents.

A suggestion was made to try to eliminate the paperwork and go to a more technological system.

Dr. Sarah Royce
Maximizing Prevention Effectiveness of Overseas Screening and Domestic Follow-Up

Dr. Royce noted that one in every three foreign born cases reported in the national statistics is reported from California. Major countries of origin include Mexico, Vietnam, and the Philippines. In 2001, California surpassed New York City in terms of incident multidrug resistant (MDR)-TB cases. The foreign born comprise 84% of the MDR cases each year.

The B notification process detects both prevalent cases as well as persons with LTBI (latent TB infection). Dr. Royce reviewed the notification process. The emphasis has historically been placed on a one way notification process, but notification is just half of the story. The feedback loop is very important to assess the success rate state-side. Examples of form 75.17 were distributed among the members of the group. Of concern is that this form is lacking key elements needed to evaluate prevention effectiveness, it is outdated, it contains no directions for completion for health department workers, 20%-40% of patients' evaluations are missing, and there is no database that goes along with this form.

The number of B notifications coming into California has risen from 2900 in 1999 to 4300 in 2001, which is nearly a 50% increase. The first measure of prevention effectiveness is the ability of the B notification program to detect cases. 3 ½ % of patients with B notification were reported within a year of arrival as cases in the U.S. If that is applied to the 400 B notification patients who came in the year 2000, it is estimated that the program detected 140 cases or 4% of California's total number of TB cases for that year. Among persons diagnosed with TB within one year of arrival, those with B notification were reported an average of 3 months after arrival, compared with 5 months for patients without B notification. Earlier case detection prevents secondary spread. Health departments are often treating these as suspected cases. Feedback to the Division of Global Migration and Quarantine will work if it can be built into the system.

In terms of measure the effectiveness of case detection, in the U.S., matches show that the yield is higher than contact investigation (in terms of cases detected/100 persons screened). 1% of all B notification patients (or 13-16% of B notification patients reported with TB in the U.S.) are smear positive. Dr. Royce then presented information about the effectiveness of the B notification system in terms of preventing future cases. Over 1/3 of B notification patients have inactive TB (TB Class 4) with a high risk of progression to TB disease. Another 10% have positive skin tests and normal chest films (classified as TB2). However, the published performance of local health departments in preventing future cases probably overestimates the actual number of cases prevented. We can't maximize the prevention effectiveness if we don't know how well local TB programs are performing. We don't know because 20%-40% of B notification patients have no evaluation results. In addition, the data collection instrument lack instructions, standard definitions, and data elements needed to assess performance. Moreover, data are not systematically used to improve overseas exams and/or domestic follow-up.

IOM recommendation 4.2 is "A pilot requiring tuberculin skin tests (TST) for immigrant applicants. If TST is positive the immigrant would need to complete treatment of latent TB infection before receiving a green card." The National TB Controllers Association (NTCA) has suggested that we need to ensure the existing B notification system is working before implementing this recommendation targeting lower risk patients. NTCA proposed a B Notification Evaluation and Improvement Initiative in a letter (distributed at ACET) calling on CDC Division of TB Elimination to take leadership; prioritize funding; provide staffing with programmatic, medical, epidemiologic, informatics expertise; improve coordination across federal programs; work with Stakeholders; and develop a plan with specific tasks and timeframes. The elements of a B Notification Plan include indicators to measure performance; national objectives; concurrence of needed data elements and revision of the collection form; an integrated information system; use of the data to improve domestic and overseas program performance; training and education (providers and patients); surveillance and research; addressing legal issues; and fiscal measures (the 1996 Welfare Reform Act made immigrants ineligible for Medicaid during first 5 years in U.S.).

Discussion Points:

Stuart McMullen stated that CDC is working on electronic notification system of B notification. There has been a document produced in draft form with identifying performance indicators. A B Notification Workgroup will be convened, which will be comprised of the pilot states that participated in the development of the TB and refugee notification system (the pilot electronic version for the notification system). A set of performance indicators will then be reviewed, and they have been distributed to the group. Annual report tables will also be reviewed. There are some delays that can be expected in the electronic notification system due to the loss of staffing in DQ. The estimated deployment of the system is in early to mid 2004 to all 50 states.

Dr. Castro stated that there is a CDC mandate to develop software that is National Electronic Disease Surveillance System (NEDSS) compliant. Thus, for the time being, the current surveillance form will be used until a TB module is created that is NEDSS compliant.

Dr. Nolan stated that efforts are needed to help foreign-born persons include the preventive interventions as they settle in the U.S., especially for immigrants who do not go through the B notification system. Dr. Royce responded that California is developing a strategic plan to look at Mexican born patients.

Dr. Anne Fanning
Report on Activities of the International Union Against Tuberculosis and Lung Disease (IUATLD)

Dr. Fanning specified that the major focus of the IUATLD is the promotion of lung health in low-income countries. The mission of IUATLD is to gather and disseminate knowledge on all aspects of TB and lung diseases and community impact; to target audiences of health workers, decision makers, and the general public; to coordinate, assist and promote work of its constituent members throughout the world; and to establish and maintain close links with WHO and other United Nations (UN) organizations, governments, and non-governmental organizations (NGOs) in health and development sectors. There are 3500 members at present from 168 countries. The work that is carried out by the organization pertains to education, technical assistance, and relevant research. The budget increase has close to doubled since 1999. The organization is funded on grants and gifts, and every penny taken in is spent. Dr. Fanning reviewed past meetings that have been held in the Middle East, China, Uruguay, and the North American region.

A review was given of the Malawi Child Lung Health Project which was funded by the Bill and Melinda Gates Foundation. The union is interested in child lung health due to the fact that issues that impede preventing death in childhood pneumonia are managerial. This project was funded in the amount of $2 million dollars. The summary of the Malawi Child Lung Health Project concluded that implementation of standard case management to district hospitals is feasible; key elements for success are supply, accountability, and supportive visits; and immediate reduction in hospital case fatality followed minimal intervention.

Regarding how to support STOP TB, Dr. Fanning indicated that there are an estimated 8.74 million cases and 1.6 million deaths; 27% of cases were reported under DOTS (00); 80% were cured under DOTS; an estimated 10.2 million will be reached by 2005 without greater effort; the goal is to find 74% and cure 84% by 2005; and quality DOTS must be expanded. Dr. Fanning concluded with a review of the benefits and responsibilities if IUATLD membership.

Discussion Points:

Msr. Stricof inquired about the Etiologic agents for pneumonia among Malawian children. Dr. Fanning responded that they were treating empirically with antibiotics.

Dr. Nolan stated that WHO established this information. Approximately 70%-75% of pneumonia cases in children in the developing world are bacterial and are drug susceptible. The drugs of choice are penicillin and cotrimoxisol for severe cases. Developing countries do not have access to cultures or to stethoscopes. It is a very algorithmic approach to diagnosis and treatments that can be conducted by people with minimal medical training.

Dr. Castro stated that streptococcal pneumonia and Hemophilus influenza would be susceptible to available vaccine interventions. He inquired about implementing that to reduce acute respiratory infection in children in Malawi. Noted was that it would also provide IUATLD with immune preventable diseases overall. Dr. Fanning stated that vaccination is an important part of the advocacy piece, however pneumococcal vaccine would not be part of that piece. She stated that on a system wide basis, developing countries do not have access to lowest cost drugs.

Many suggested that the concept of sustainability should be challenged. Dr. Fanning stated that the union should be sustained as well as expand. Many agreed.

Dr. Eric Blank
Report on the 4th National Conference on Laboratory Aspects of Tuberculosis

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Dr. Blank indicated that he was representing the Association of Public Health Laboratories. He then reported on the 4th National Conference on Laboratory Aspects of Tuberculosis convened December 10-13, 2002. The conference was held in San Francisco, with 200 participants in attendance. The attendants represented the following areas and/or organizations: Clinical and public health laboratories; clinicians; TB controllers; PHPPO/DLS, NCID/DASTLR, NCHSTP/ DTBE; and funding support from CDC/PHPPO/DLS.

The conference had a dual focus: 1) Integration of laboratory services; and 2) An update on laboratory technology and appropriate uses. Among the examples of topics that dealt with the lab program and clinician integration were global epidemiology, the issue of TB and BT, perspectives of a clinician, TB infection and diagnosis, perspectives of a TB controller, the issue of partnership, communication, networking within the states between laboratories, clinicians and the TB programs, and international collaboration. The technical laboratory issues discussed included drug sensitivity testing (DST); molecular detection of resistance; fingerprinting; NAAT; sequencing; MIDI/HPLC; QFT; biosafety; specimen collection; and packaging and shipping.

Dr. Blank noted that the 4th National Conference dealt more with bringing the participants up to speed in terms of available technology and integration. In the IOM report (appendix D) there was discussion that the public health laboratory community needed to determine how to approach the issue of accessibility and availability of laboratory services. The IOM report recognized the importance of quality laboratory services in meeting objectives and eliminating TB in the U.S. There is a declining incidence of TB, and there has been essentially flat funding to the states for TB services. While the funding has continued to the programs within the states, the programs determine how much money to allocate to the laboratories. The result, from a laboratory point of view, is reduced funding.

Proposals have been put on the table for regionalization, (RFLP regionalization model), which did not sit well with the public health laboratory directors. The group wanted to study the issue of the prescriptive levels of service models that have been presented at previous national conferences. The goal of the task force is to improve TB control through optimal use of laboratory services and effective reporting and tracking of information. The task force has identified certain principles for the present as well as the future: 1) A public health imperative to eliminate TB; and 2) Effective TB control which depends on integrated system that includes clinicians, laboratories and TB controllers; effective public/private partnerships (80% of the TB laboratory work is not done by the state public health laboratory, but by the private sector); network of laboratories incorporating private and public laboratories; and timely and complete communication between the laboratory network, TB control programs, and health care providers (must have follow up in a timely manner).

The principle is that each jurisdiction must assure access to the appropriate levels of quality TB testing and complete, timely reporting. All states/jurisdiction must perform a true cost ongoing assessment of TB laboratory services which includes costs for laboratory services (including support for outbreak investigations, and detection of MDR-TB); training pertaining to communication systems including computers and LIMS within each jurisdiction; optimal testing and referral systems, including implementation of new technologies; and the public and private sectors.

The jurisdictional strategic plan must include a systems approach to assure quality, proficiency, appropriate use of new technologies, repository of isolates and fingerprinting capability, a timely flow of information, and training. A process that is very critical is to perform a true cost assessment of the TB laboratory services; this is a very global cost assessment. Outcome measures include the national objective to eliminate TB (1 case/ 1,000,000) by the year 2010; that all newly diagnosed infectious cases of TB should be started on appropriate treatment within 48 hours of specimen collection; and an increased turnaround time (TAT) for smears, cultures, and drug sensitivity tests (DST).

The next steps are: ACET in February 2003; 2nd Task Force meeting; partner organizations through June 2003 (e.g., NTCA, ASM, ALA, ASCP, APHL, and many others); final report to the APHL board by summer 2003; APHL approved report issued publicly to ACET at the end of summer 2003; and advocacy and marketing.

Dr. Blank concluded with a discussion of implementation of buy-in throughout the healthcare system, as well as buy-in from policy makers to provide adequate funding. He stressed that there should be better application of technologies and services to achieve these objectives.

Discussion Points:

Dr. Castro inquired what assistance ACET could contribute in helping to achieve the benchmark issues raised. Dr. Blank responded that benchmarks concerning cost assessment, strategic planning, and the assessment of the laboratory services within the jurisdiction needs to be done by the jurisdiction. The Task Force is going to work very hard on having individual jurisdictions carry out the recommendations of the Task Force.

Dr. Castro expressed concern that data must be systematically obtained, and some may include direct costs, while some may not. Dr. Blank reiterated the issues that have been taken into account by the Task Force.

Dr. Kawamura inquired about how to bring private laboratories up to speed with the public health laboratories. The problem is with the private laboratories that are not following reporting guidelines, or which do not have the services available for DST. Dr. Blank responded that Clinical Laboratory Improvement Amendments (CLIA) standards apply to public as well as private laboratories. The real problem that has been identified is that it is not a simple matter pertaining to why a laboratory provides that service in the private sector—it may be an economical issue.

Dr. Fanning commented on the importance of a link between public health and the laboratory, and also stated that the link was missing in international laboratories as well as domestic laboratories.

Dr. Blank stated that DCLS is leaving the door open to regionalization, however, it has not been completely thought through.

Dr. Castro expressed interest in hearing more about discussions pertaining to newer tests concerning latent TB testing, noting that in the past, the laboratory has not had a role in diagnosing latent TB. He also recommended joining forces with the private providers, looking at the largest labs and inviting them to the table, given that they should be part of the process as well as the solution. Dr. Blank responded that there is a representative from Labcorp on the Task Force, and that there was much interest from DCLS in ACET. It was suggested by Dr. Valdiserri to have a member from ACET act as a liaison to DCLS to keep the group abreast of the current issues.

Dr. Stephanie Bailey
Update on ACET workgroup on TB in Southeastern States and U.S. born African Americans

Dr. Bailey briefly reviewed the TB in African-Americans and Southeastern States Meeting planned for May 13-14, 2003 in Atlanta, Georgia. The purpose of this meeting is to raise awareness of the disparity in rates of TB in U.S. born African Americans compared to other U.S. born persons, solicit support for eliminating TB in U.S. born African-Americans, and develop recommendations for accelerating the decline in TB rates among U.S. born African-Americans in the Southeastern states. Several goals have been outlined for this consultation so that by the end of the meeting, participants will:

- Know the rates of tuberculosis in U.S. born African-Americans and recognize the disparity in rates of tuberculosis compared to U.S. born persons in the Southeastern states;
- Understand the root causes of, and areas in need of study to elucidate reasons for the disparity in rates of tuberculosis in U.S. born African-Americans in the Southeastern states;
- Understand the role of state and local TB control programs in preventing, controlling, and eliminating TB;
- Understand the role of communities and community organizations in preventing, controlling, and eliminating TB;
- Understand the role of community mobilization in preventing, controlling and eliminating TB; and
- Develop recommendations in the following areas:
  - Increasing awareness in the African-American community and the Southeastern states about TB;
  - Mobilizing community resources to eliminate TB in the African-American community and the Southeastern states; and
  - Improving relationships with the African-American community to enhance TB elimination in their community.

Proposed invitees include the President of the Bishops Council for the African Methodist Episcopal Church, the President of the American Medical Association, the Chairman of the Congressional Black Caucus, The Executive Director of the Congress of National Black Churches, The CEO of the NAACP, The President of the National Baptist Convention of America, the President of the National Baptist Convention U.S.A., The Executive Director of the National Black Catholic Congress, The President of the Urban League, Tom Joyner (radio personality), the President of the Associated Black Charities, and others. A publication of recommendations will follow the meeting.

Discussion Points:

Given that this is a joint consultation with ACET and CDC, Dr. Valdiserri reminded his

colleagues that any time Members of Congress are invited to a CDC meeting, that invitation does have a specific protocol and needs to go through the Policy Office before any invitation is made. He also noted that the ramifications of inviting media to this conference need to be considered.

Ms. Stricof commented about the second goal, noting that she really did not see a working group focusing on that. One presentation at the beginning of the meeting will not be sufficient to encompass the entire issue. She asked Dr. Bailey how she was going to ascertain this information dealing with specific areas and specific sub-populations of individuals. Dr. Bailey responded that the invitees are not scientists, nor are they researchers. The conference is to increase awareness, number one, and then encourage people to help develop a solution to how to motivate communities around these issues. However, Dr. Bailey stressed that Ms. Stricof's consideration will be taken into account.

Dr. Hewitt stated that the African-American community is a heterogeneous community rather than a homogenous community. Caribbeans, African-Americans, and other sub-groups are included in the African-American community. These groups may have been born in the U.S., but have very different cultural characteristics. Consultations should be made with colleagues in syphilis, where a syphilis elimination plan has been developed. There is a process that was followed, and there were expectations and money. Eliciting the support of the African-American community raises the question of whether this will be yet another discussion of problems in a way that adds to a burden that may not be very critical in the grand scheme of things. He inquired as to whether this conference was designed to do something about TB, and if so, what? It is important to understand wounds, attitudes, and behaviors that may exist prior to that.

Dr. Hewitt stated that the invitees seem very capable, however, celebrities and those individuals on the invitee list are not the "community." It will be a very different conversation, but one that is not very community focused. These invitees will ask some very poignant questions about how they might be able to help, and they better have a very good idea about what they will do for the cause, and what the organization will do for them.

Dr. Castro acknowledged that individuals who will be attending may have no scientific background. However, getting people involved in the fight against TB is very powerful.

Dr. Gene Migliaccio and Dr. Ken Castro
Update on CDC/INS Discussions to Improve Completion of TB Treatment

Dr. Ken Castro reminded the group that it was through deliberations of ACET that the need arose to address unmet needs of persons who were INS detainees with tuberculosis who had not completed therapy. CDC staff have met with INS staff on this issue 3 times.

Dr. Gene Migliaccio briefed the group on an update. This is a success story, because it was the identification of the problem in terms of releasing INS detainees before the course of treatment was completed. This was identified by ACET and recommendations were made and accepted. The INS and CDC collaboration began about 4 months ago, with good representation from both. CDC has engaged many main offices such as The Office of General Counsel, The Office of

Policy, and The Office Field Operations. Both groups are committed to making results happen.

Dr. Migliaccio thanked Dr. Charlie Nolan for his leadership, and Dr. Valdiserri, Dr. Castro, and Dr. Lobato from CDC for making the trip to Washington to make this a reality.

Dr. Migliaccio then framed a problem, pointing out that the Public Health Service (PHS) has been taking care of INS detainees, and that this has been a longstanding relationship. On any given day, 22,000 individuals who are detained by the U.S. are taken care of by PHS. Out of the 22,000, approximately 5,000 individuals are held in 12 INS service processing centers located throughout the U.S. The other 17,000 are held in over 500 jails throughout the U.S. INS leases beds in these jails due to the fact that they do not have the capacity to house all of the detainees. Over the last few years, The Division of Immigration Health Services has been processing 225,000 individuals (annually) as new entries.

The many immigrants that are here illegally compound the problem of trying to manage a TB program in over 500 sites. CDC and INS have to have a commitment. Local partnerships are being developed at health departments, as well as within laboratories. Of importance is to develop a partnership with the jails that INS utilizes, to assure that when a case of TB is identified, a course of treatment is initiated. This treatment must be initiated prior to being released into the U.S. or deported. It does not appear at this time that there will be any short-term legislative fix to address this issue. The group has been more focused on changes in procedures and policies, that will aid in addressing this issue in the future. There has been ongoing support from the Office of General Council from CDC and INS.

Dr. Diana Schneider
Immigration and Naturalization Services (INS)

Dr. Schneider indicated that the INS is in the process of conducting analysis, and that she would like to present a formal presentation to ACET once that data are complete. INS has been holding meetings, since November, approximately every 5 weeks. The first task was to conduct analyses of the population at the service processing centers, which are the facilities were Immigration Health Services (IHS) has direct care staff. There is currently no data on the INS populations that are held in the jails. Some findings pertained to looking at country of origin and active TB cases. The results showed that about 44% of active TB cases were from Mexico. Also considered was release status, which refers to whether an immigrant is to be released into the U.S. or deported. Findings showed that most of the Mexicans with TB were deported. The second most prominent country represented was Honduras, followed by Guatemala.

Two years of data were collected for fiscal years 2001 and 2002. There were 93 active TB cases. This only accounts for about 1/3 of the INS population. The other 2/3 are held in the jails, for which there is no data. There have been very good discussions within the INS Office of General Council concerning conditions of release. In the event an individual is to be released into the U.S., they receive order conditions. The order conditions are either pre-custody or post-custody order conditions. The order is order of removal. Sometimes individuals are released in the U.S. until their INS hearing, but may be deported at a later time depending on the status and legal

situation of the individual. The pre-order conditions are imposed before an individual is brought into detention. In the opinion of legal counsel, health status is not a good legal vehicle to base conditions of release upon. The reason is the statutory authority for using detention as a vehicle for removal, which is deportation. Thus, the reason to detain based on health status could be very seriously challenged in court.

Post-order conditions would apply once a detainee is in custody. If an individual is to be released into the U.S., the post-order conditions would contain "conditions related to reporting for therapy." The post-order conditions have enforcement capabilities. For example, conditions could be attached stating that the immigrant must continue with therapy, and provide documentation to this effect. In the case of non-compliance, they are brought into detention. That is being explored in legal counsel.

There have been a number of policies and procedures needed to strengthen notification of TB cases. The findings are that multidirectional notification is needed. The relationships between IHS, INS, jails, and health departments could be strengthened so that communication occurs between all. Jails may not know that they are required to report TB to the health department, especially jails that have the TB evaluation done in hospitals. More education will be provided and INS policies will be strengthened in requiring the jails to report to INS.

Communication between all of the parties is key. As a result of these discussions, it was decided it would be important to invite representatives from the health departments and the National Tuberculosis Controllers Association to participate in future meetings. INS has agreed to add language to policies and attention standards in regard to the jails notifying INS when active TB cases are present. The Point of Contact for TB will be a managed care coordinator. As standards and policies change and are modified to address TB, a process of educating the jail staff needs to be implemented as well. INS will be developing a strategy to address this issue.

Discussion Points:

A question was raised regarding liability issues for contract jails. The response was that the jail is liable if an individual enters the jail and infects others with TB. INS is encouraging the jails to notify someone when an individual is identified with TB. All Jails should have a TB training program as part of their accreditation.

Many complemented the work that has been done, stressing that tremendous benefits should be seen from this work.

Mr. Scott McCoy
Plans for World TB Day 2003

Mr. McCoy presented an overview on World TB Day 2003. The current resources are provided by the Division of TB Elimination (DTBE). The current resources being used are fact sheets and posters. Links to World TB Day Planning resources can be accessed at http://www.vfv.gov/ftb. There will be 3 articles in the *MMWR* , including a notice to readers about World TB Day, an

article announcing provisional 2002 surveillance data, and an article on results of the TB screening project in Botswana. The World TB Day planning group will be providing ideas and resources, developing messages targeted to localities (e.g., high medium and low incidence states), and will be meeting the week of February 17 to finalize plans. The Binational TB Card Pilot Project Event will also be introduced. The purpose of this pilot is to educate key audiences about the continuity of care and the expected treatment outcome improvements.

There are many partners in the Binational TB Card Pilot Project including the following: Mexican Ministry of Health, Texas Department of Health, California Department of Health, U.S./Mexico Border Health Commission, U.S. Agency for International Development, Health Resources and Services Administration, Binational Tuberculosis Project "Juntos," and La Fe Community Health Center. The Key audiences within the key states will be TB controllers, leaders of at-risk communities, policy makers, health care workers, Federal Employees working in immigration, and the media. The expected outcomes are to inform key audiences about project operations, to inform policy makers about the need for the project, to provide international media exposure, and to raise the public's general awareness of the project. The key states targeted are California and Texas in the U.S., and Baja California, Sonora, Chihuahua, Coahuila, Nuevo Leon, and tamaulipas in Mexico.

Discussion Points:

An inquiry was posed regarding the states. The Denver Metro TB Clinic now requires new clinical staff members be fluent in Spanish since 65% of the patients speak Spanish only. The information should not be limited to the border states. Mr. McCoy stated that it is the border states that are putting there resources into this event, and that all of the materials are being printed in English and Spanish.

Other Business

Previous Minutes

Dr. Charlie Nolan made a motion to accept the minutes of November 7, 2002. The group asked for any corrections. With none posed, the minutes were accepted.

Awards

Dr. Charlie Nolan was presented with a plaque from the ACET group for his hard work and dedication. Dr. Nolan quoted Theodore Roosevelt who said, "Life's sweetest joy is the opportunity to work hard on work worth doing."

INS Report

Dr. Castro stated that as a result of discussions, an INS report has been drafted, but the wording needs to be updated. The three case scenarios with implications have been agreed upon. He asked the council how this could be done in an expedient manner. It was clarified that there have been some issues regarding clearance of this document, which should have been published months ago. Dr. Castro stated that new data could be included. It was suggested that this issue would be better discussed in a smaller group. INS data cannot be released without their agreement.

Agenda Topics

The following suggestions were made for possible future ACET meeting presentations:

- Stop TB Partnership at WHO
- Cross border issues related to aboriginal TB burden (Canada is very concerned about its aboriginal TB, for example)
- Update from USAID
- Review of targeted testing programs that currently exist given that targeted testing becomes more important the closer TB elimination becomes
- TB 101 presentation for the new members at the next meeting
- Dr. Morris should give an update of the work that is being done towards new TB vaccines

Certification of the Minutes

I hereby certify that to the best of my knowledge, the foregoing Minutes of the proceedings are accurate and complete.

_____ _____

Charles M. Nolan, M.D., ACET Chair **Date**

End of Minutes